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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,791	02/27/2006	Yorimasa Suwa	1254-0305PUS1	6478

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
11/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/569,791	SUWA ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,23-39 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,23-39 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 7/9/09 have been fully considered but they are not persuasive.

Claims 40-41 have been cancelled. Claims 42-44 have been newly added.

The rejection of claims 9, 23-27, 32-33, and 38-41 under 35 U.S.C. 102(e) as being anticipated by Ota et al. (U.S. Patent Application Publication 20070105122 A1) is withdrawn in view of the amendments to the claims. It could be reapplied if the new matter rejection set forth below is overcome.

The rejection of claims 9, 23-33, and 38-41 under 35 U.S.C. 102(e) as being anticipated by Wu et al. (U.S. Patent Application Publication 20070224201 A1) is withdrawn in view of the amendments to the claims. It could be reapplied if the new matter rejection set forth below is overcome.

The rejection of claims 34-35 under 35 U.S.C. 103(a) as being unpatentable over Wu et al. in view of the specification at page 15 is withdrawn in view of the amendments to the claims. It could be reapplied if the new matter rejection set forth below is overcome.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 23-39, and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is both a new matter rejection as well as an enablement rejection.

Claims 9 and 23 have been substantively amended and claim 44 has been newly introduced.

Applicant points to claims 40-41 as basis for the limitation "wherein said candidate substance is a substance that has not yet been determined to be an antidiabetic." This is not agreed with. Claims 40-41 (now cancelled) were not original claims and were considered to constitute new matter. (See amendment adding these claims dated 5/12/08 and new matter rejection for these claims dated 8/21/08.) There is no basis for this limitation in claims 9, 23, and 44.

Applicant also points to the fourth paragraph on page 15 of the specification for basis. This paragraph is reproduced below:

The candidate substance judged as having interaction with the protein according to the present invention by the screening method of the present invention means that the substance has been screened as a novel antidiabetic having the mechanism of pharmacological action similar to that of the thiazolidine derivative.

This does not form basis for the step of "determining that the candidate antidiabetic substance has a pharmacological action similar to that of the thiazolidine derivative" as now recited in claim 9, 23, and 44. There is no determination step disclosed or contemplated in this paragraph.

The paragraph on page 15 makes an assumption that interaction of the protein with the candidate substance alone leads to the conclusion that the substance a mechanism of pharmacological action similar to that of the thiazolidine derivative. There is reason to doubt the objective truth of this assertion.

The specification discloses that FLJ14797 or SEQ ID NO: 2 binds to pioglitazone, a known antidiabetic substance. See pages 10 and 24-25. The specification does not disclose that SEQ ID NO: 2 (or derivatives thereof embraced by the claims) binds to rosiglitazone, troglitazone (**note that this compound's name is not spelled correctly in the claims**), or ciglitazone.

The specification discloses that compounds A-1, A-2, and A-3 bind SEQ ID NO: 2. The structures for A-1, A-2, and A-3 are provided on pages 16-17 of the specification. The specification does not disclose that compounds A-1, A-2, and A-3 have the mechanism of pharmacological action similar to a pioglitazone, rosiglitazone, troglitazone, or ciglitazone. The specification does not establish that compounds A-1, A-2, and/or A-3 have any antidiabetic properties.

It is noted further noted that US Patent Publication 2008/0102457 (corresponding to co-pending application 11/718,946) has several inventors in common with the instant application. This application was filed **after** the instant application. It also discloses FLJ14797. SEQ ID

NO: 16 of US Patent Publication 2008/0102457 corresponds to SEQ ID NO: 2 of the instant application. It is interesting to note that this reference **does not assert** that substances that bind to it are antidiabetic compounds. Rather, FLJ14797 is disclosed as binding ketanserin. Other compounds that bind to FLJ14797 are disclosed as being 5-hydroxytryptamine receptor antagonists or antihypertensive drugs. See at least claims, SEQ ID NO: 16, paragraphs [0054, 0446], and Table 7-2. Thus, applicant's own disclosures demonstrate that screening for the presence or absence of any interaction between the candidate antidiabetic substance and the target protein of SEQ ID NO: 2 **alone** will not identify an antidiabetic compound. At the time of the invention, applicants themselves did not know what the pharmacological mechanism or properties of SEQ ID NO: 2 were.

It is again noted that pioglitazone was already known and characterized as an antidiabetic. Its interaction with SEQ ID NO: 2 did not identify or characterize these properties. The specification provides no example elucidating the role of SEQ ID NO: 2 in diabetes. There is no evidence of record establishing any role of SEQ ID NO: 2 in diabetes. The specification does not demonstrate that any novel compounds identified as interacting with SEQ ID NO: 2 have any antidiabetic properties. Applicant is again reminded that pioglitazone (for example) has uses in addition to applications in diabetes. Again for example, Hobbs et al. (U.S. Patent No. 7,034,056) discloses uses of pioglitazone in treating obesity. (See at least claim 26.) Again for example, Chandraratna et al. (U.S. Patent No. 7,105,566) discloses uses of pioglitazone in treating vascular trauma. (See at least claim 16.) Thus, the final step of determining that the candidate antidiabetic substance has a pharmacological action similar to that of the thiazolidine

derivative **is not** a determination that the candidate antidiabetic substance has **antidiabetic properties**. The claims do not require a determination of antidiabetic properties.

Part (b) of claims 9 and 44 are directed to mutated proteins. However, the specification does not specifically describe nor exemplify any mutated proteins within the scope of the claims that interacts with any antidiabetic compound. It is unclear what mutated proteins would retain those structural and functional features required by the claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. In the instant application, there are no working examples, there is no specific guidance as to mutated proteins of SEQ ID NO: 2, the prior art does not recognize SEQ ID NO: 2 as being involved in diabetes, and the claims are broad. It is not considered to be so predictable that any compound that interacted with SEQ ID NO: 2 or a mutated version thereof would possess antidiabetic properties. The claims are considered to require undue experimentation to practice.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa